

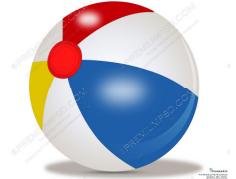


NORTH DAKOTA  
DEPARTMENT of HEALTH

# Immunization Newsletter



## National Immunization Awareness Month



Each year in August, National Immunization Awareness Month (NIAM) provides an opportunity to highlight the values of immunizations. Activities focus on encouraging all people to protect their health by being immunized against infectious disease. The NIAM Communication Toolkit that was developed by the National Public Health Information Coalition (NPHIC) in collaboration with the Centers for Disease Control and Prevention (CDC) has four weekly themes to focus on:

- A Healthy Start (August 3 through 9)
- Back to School (August 10 through 16)
- Off to the Future (August 17 through 23)
- Not Just for Kids (August 24 through 30).

This toolkit includes many key messages, sample media materials, social media content, and event ideas. This toolkit is to help promote the importance of immunizations during NIAM, but the resources in the toolkit can be used throughout the entire year. The toolkit can be found at <https://www.nphic.org/niam>.

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### ***Epidemiology and Prevention of Vaccine Preventable Diseases 13th Edition- The Pink Book***

The North Dakota Department of Health (NDDoH) has purchased one copy of *Epidemiology and Prevention of Vaccine Preventable Diseases 13th Edition – The Pink Book* for each Vaccines for Children Program (VFC) enrolled provider in the state. The Pink Book provides health care providers with the most comprehensive information about immunizations and vaccine preventable diseases. The Pink Book is also available online at <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>. The online version includes updates from the printed version.

- New chapter on vaccine administration
- New recommendations regarding selection of storage units and temperature monitoring tools
- New recommendations for vaccine transport
- Updated information on available influenza vaccine products
- Updates on use of Tdap in pregnancy and in persons 65 and older
- Use of PCV13 and PPSV23 in adults with immunocompromising conditions
- New licensure information for varicella-zoster immune globulin

The 13th Edition of The Pink Book includes:

*(Continued on next page)*

The 13th Edition of The Pink Book does not include:

- February 2015 Advisory Committee on Immunization Practices (ACIP) recommendations for HPV9 or meningococcal B vaccines

The CDC is hosting Pink Book NetConferences every Wednesday at 11:00 AM (CST) starting July 8. Interested providers can register at

<http://www.cdc.gov/vaccines/ed/webinar-epv/index.html>. The NetConferences are also being archived on the website as well.

Additional copies of this book are available for purchase from the Public Health Foundation at <http://bookstore.phf.org/Default.aspx?TabID=251&productId=27876>. Please feel free to contact the NDDoH Immunization Program with any questions or concerns at 701.328.3386 or toll-free at 800.472.2180.

## ACIP Update

The Advisory Committee on Immunization Practices (ACIP) met June 24 and 25. Below is a summary of recommendations made at that meeting. This summary was provided by the Immunization Action Coalition. However, the ACIP-approved recommendations do not become official until they are approved by the CDC director and published in the Morbidity and Mortality Weekly Report (MMWR).

### Influenza vaccine

ACIP approved another revision of the algorithm for determining the number of influenza doses needed for children 6 months through 8 years of age. The revised algorithm is simpler because consideration of doses of the 2009 monovalent H1N1 influenza vaccine has been removed.

### Meningococcal B vaccine

ACIP had an extensive discussion about the use of serogroup B meningococcal (MenB) vaccine among healthy adolescents. In general, healthy is considered those that do not have conditions that put them at increased risk of meningococcal disease—persistent complement component deficiency, anatomic or functional asplenia, certain microbiologists and those identified to be



at increased risk because of a meningococcal B outbreak. Recommendations for MenB vaccination of persons at increased risk of meningococcal disease were published in the June 12 issue of MMWR, pages 608–612.

ACIP voted to recommend that a MenB vaccine series may be administered to persons 16 through 23 years of age with a preferred age of vaccination of 16 through 18 years. This Category B (permissive) recommendation allows for individual clinical decision-making, and will enable coverage of MenB vaccines by the VFC program and most insurance plans.

No preference was stated for the use of either of the two currently licensed MenB vaccines, Bexsero® (Novartis) or Trumenba® (Pfizer). However, because the vaccines are antigenically different, the same product should be used to complete the series for each of the vaccines. Bexsero® is a two-dose series and Trumenba® is three doses.

Both vaccines are available for order from the VFC program. Bexsero® is available in one dose increments and Trumenba® is only available in ten dose increments.

## **Pneumococcal vaccine**

ACIP is aware that the different recommended intervals between pneumococcal conjugate (PCV13) and pneumococcal polysaccharide (PPSV23) vaccines for different ages and risk conditions are confusing to clinicians. For instance, currently the recommended interval between PCV13 and PPSV23 for healthy persons age 65 years and older is 6 through 12 months, but the recommended interval if PPSV23 is given first is one year. The recommended interval between any sequence of PCV13 and PPSV23 for children age 2 through 18 years at increased risk of invasive pneumococcal disease is eight weeks.

ACIP discussed this issue at length in an attempt to harmonize the intervals between risk groups and ages. Unfortunately there are few studies that have systematically examined the immunologic effect of various intervals between PCV13 and PPSV23. After discussing the available evidence on the issue, ACIP voted to change the recommended interval between PCV13 and PPSV23 from the current “6 through 12 months” to “one year or longer” for healthy persons age 65 years and older (that is, the interval will be one year or longer regardless of whether PCV13 or PPSV23 is given first). The recommended interval between PCV13 and PPSV23 for persons younger than age 65 years at increased risk of invasive pneumococcal disease was not changed. ACIP reiterated that PCV13 and PPSV23 should not be administered at the same visit. However, doses given at an interval shorter than the recommended interval do not need to be repeated.

## **Smallpox vaccine**

The only smallpox vaccine currently available in the U.S. is ACAM2000 (Acambis®). The most recent recommendations for the use of smallpox vaccine among laboratory personnel were published in 2001. ACIP approved a revised document on smallpox vaccination of laboratory

personnel who directly handle either cultures or animals contaminated or infected with replication-competent vaccinia virus, recombinant vaccinia viruses derived from replication-competent vaccinia, or other orthopoviruses that infect humans, such as monkeypox, cowpox or variola (smallpox). ACIP also recommends that vaccination can be offered to health care personnel whose contact with replication-competent vaccinia viruses is limited to contaminated materials (such as dressings) or those who administer ACAM2000.

## **General Recommendations on Immunization**

The ACIP statement titled *General Recommendations on Immunization* is revised every three to five years. Revision of this important document has been in progress since the current version was published in 2011. ACIP approved the final sections of the revised document (altered immunocompetence, vaccination programs, vaccination records, and sources of vaccine information). The full revised document will now enter internal CDC clearance. Publication of the revised document is anticipated to be mid-2016.

## **HPV vaccine**

At their February 2015 meeting, ACIP voted to include the newly licensed 9-valent human papillomavirus (9vHPV, Gardasil 9®, Merck) vaccine to the vaccines available for use within the current HPV recommendations. These recommendations were published in the March 27 issue of MMWR, pages 300–302.

During the weather-shortened February 2015 meeting, time did not allow a discussion of the use of 9vHPV vaccine for persons who have previously completed a full HPV vaccine series. This issue was discussed at the June meeting, and ACIP did not take a vote either to recommend or to not recommend routine revaccination of persons who have previously

received a full series of either the 2- or 4-valent HPV vaccine. The benefit of protection against the five additional types included in 9vHPV is primarily for females for protection against cervical cancers and precancers. Only a small percentage (about 4%) of HPV-associated cancers in males are caused by the five additional types included in the 9-valent vaccine. However, a study has shown no serious safety concerns among females revaccinated with 9vHPV after a series of 4vHPV.

No ACIP recommendation means that the VFC program and insurance plans will most likely not cover revaccination. At the conclusion of the discussion ACIP requested that the HPV Work Group reconsider a permissive recommendation



(Category B-similar to the recommendation made for MenB vaccine for healthy adolescents) for revaccination, which would enable coverage by the VFC program and some insurance plans for clinicians or patients who wish to be revaccinated. This issue will likely be discussed again at the October 2015 meeting.

The official minutes and presentation slides from the June meeting will be available on the ACIP Meeting Information web page within the next few weeks.

## **Catholic Medical Association Position Paper on HPV Immunization**

The following is a position paper published by the Catholic Medical Association (CMA) on January 18, 2007.

*On June 8, 2006, the U.S. Food and Drug Administration (FDA) approved Gardasil®, a vaccine against human papillomavirus (HPV) types 6, 11, 16, and 18, for the use in girls and women 9 to 26 years of age. On June 29, 2006, the Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination of girls at 11 to 12 years of age, with catch-up vaccination of girls and women 13 to 26 years of age. Many parents have asked whether this vaccine is morally licit and whether this recommendation for broad use is warranted. In addition, some public health agencies and legislatures are considering whether immunization for HPV should be made mandatory for school attendance. This statement outlines the Catholic Medical Association's position on these issues regarding HPV vaccine.*

### **Significance of Addressing HPV**

*HPV cause genital warts and anogenital cancers, including cervical cancer. More than 40 HPV types can infect the genital tract, but about 70% of cervical cancers are caused by types 16 and 18, and about 90% of genital warts are caused by types 6 and 11. Each year in the U.S., an estimated 6.2 million persons acquire new HPV infections annually; 9,710 new cases of cervical cancer are diagnosed; and the disease kills about 3,700 women. The number of lifetime sexual partners is the most important risk factor for genital HPV infection. In a study among college women, HPV infection rose to 40% within two years after commencement of sexual activity. Condoms provide, at best, marginal protection against HPV.*

### **The HPV Vaccine**

*A multicenter, randomized, double-blind trial enrolled 552 women 16 to 23 years of age in the United States, Scandinavia, and Brazil, who were given 3 doses of vaccine or placebo over 6 months. Over the 36-month study period, the vaccine demonstrated 89% efficacy against persistent infection and 100% efficacy against disease*



(warts, neoplasia, or cancer) caused by the 4 HPV types contained in the vaccine. Data submitted to the FDA (and summarized in the manufacturer's prescribing information) demonstrated similar efficacies in larger cohorts of women and that the vaccine produced anti-HPV antibody titers in girls 9 to 15 years of age that were non-inferior to those produced in women 16 to 26 years of age. The duration of efficacy of the vaccine is not yet known, booster injections may be required for sustained immunity. Testing in males is underway.

The HPV vaccine appears to be safe. Like other injected vaccines, HPV vaccine causes pain, swelling, and erythema at the injection site. Fever was reported in 10.3% of Gardasil® recipients, compared to 8.6% of placebo recipients. No serious adverse events were attributed to Gardasil®.

The 3-dose Gardasil® vaccine series costs about \$350. Cost-effectiveness models have estimated about that, overall, a program of universal vaccination of adolescent girls will cost \$23,000 to \$45,000 per quality-adjusted life year saved. These cost-benefit ratios fall within range generally deemed acceptable for preventative medicine.

### **Does the CMA Support Use of the HPV Vaccine?**

The CMA supports widespread use of Gardasil® for girls and women in the age range for which the vaccine has been recommended by the ACIP, because it is effective, safe, and ethical to use, provided certain conditions are met.

#### **1. Is Use of the HPV Vaccine Ethical**

There is no ethical objection to the HPV vaccine either as a strategy against disease or in its production. Patients and parents must have the opportunity to give informed consent to its administration.

### **Ethics**

The fact that HPV is spread primarily by sexual contact does not render vaccination against it unethical. Healing and preventing disease, no matter what their source, are acts of mercy and moral good. Prevention of HPV infection is distinct from, and should not be construed as encouraging, the behavior by which HPV is spread.

### **Production**

Gardasil® is composed of recombinant type-specific capsid proteins that are expressed in yeast and that aggregate spontaneously into virus-like particles. Its production does not involve cell lines derived from tissues of intentionally aborted babies as do other common vaccines such as those against hepatitis A, (some) rabies, rubella, varicella, and zoster.

### **Informed Consent**

Generally accepted principles of informed consent include disclosure (of benefits, risk, and alternatives), understanding and voluntariness. (Regarding voluntariness, see the discussion of mandates for the HPV vaccine, below.) In addition to the basic facts summarized in the manufacturer's prescribing information, physicians should ensure that patients and parents understand that:

- Although Gardasil® covers HPV 16 and 18, which account for 70% of cervical cancers, 11 other high risk strains of HPC exist that cause cancer.
- The duration of efficacy of the vaccine is not yet known. Booster injections may be required for sustained immunity.
- There are effective alternatives for preventing cervical cancer. For example, as a result of routine Pap smears over the past 50 years, the age-adjusted incidence of cervical cancer in U.S. women declined from 14.8/100,000 in 1975 to 7.1/100,000 in 2003; and during that time, the age-

*adjusted mortality from cervical cancer decline from 5.6/100,000 to 2.5/100,000.*

## **2. Should the HPV Vaccine Be Mandated?**

*Public health officials and legislators across the country are discussing whether the HPV vaccine should be required for attendance at school by girls  $\geq 9$  years of age. Indeed, in some areas, public officials have been faced with intense lobbying efforts to mandate the use of this vaccine. The CMA opposes mandating the use of HPV vaccine, as well as direct or indirect efforts to pressure parents or minors to accept it.*

- HPV vaccine is a medical treatment, and under natural and civil law, it is parents who have the primary authority and responsibility to raise their children and to approve medical treatments for them. Addressing the issue of sexually transmitted infections (STIs) is a part of parents' indispensable task of teaching their children about sex and forming them in chastity. Using mandates or other pressure (such as threatening to exclude children from attending school) violates parental rights and undermines parents' authority.*
- While Gardasil® appears to be safe, effective, and ethical; there is always risk, however small, with any vaccine. Moreover, there are valid alternatives for avoiding or monitoring for HPV infection.*
- To justify withholding educational opportunity from students whose parents believe that vaccination is not in the students' best interest, at least the following conditions should be met:*
  - 1. The disease is potentially serious;*
  - 2. Non-vaccinated students would pose a substantial risk to others were they allowed to attend school;*
  - 3. The vaccine that prevents it is safe and effective;*

- 4. The vaccine meets reasonable standards for cost-effectiveness; and*
- 5. The vaccine is provided to students who cannot afford it.*

*Criterion #2 is not met by HPV infection. We presume that genital HPV infection is not transmitted while students are in school, excluding non-vaccinated students from school would not prevent extramural transmission.*

- Given the importance of parental involvement for raising children, and particularly in forming their children in chastity, it would be counterproductive to override their ethical objections and negate their authority on this issue.*

## **3. How Can HPV Immunization Programs Best Serve the Health of Patients and Society?**

*Physicians should take advantage of questions about or requests for HPV vaccination to address broader adolescent health issues. Campaigns for widespread immunization against HPV should not undermine efforts to reduce non-marital sexual activity and to promote chastity.*

*A visit to the clinic for vaccination against HPV infection, as well as tetanus, diphtheria, pertussis, and meningococcal disease, presents an opportunity for the physician to discuss the broader range of health issues faced by adolescents. Such issues include the benefits of healthy eating and regular exercise, as well as the risks posed by drug and alcohol use, driving while intoxicated, and extramarital sexual activity. To the greatest extent possible, physicians should respect and support parents, who have the primary responsibility for protecting and raising their children, and assist them in this task.*

*At the same time, support Gardasil® and future vaccines against STIs should not undermine efforts by physicians, parents and society to promote chastity because:*

- Neither Gardasil® nor other vaccines can address the many other harmful STIs that are prevalent at high levels,
- There are significant, harmful, non-infectious sequelae of premarital sexual activity that cannot be prevented by any vaccines, including increased risk for depression, suicidal ideation, and future divorce, and
- Premarital sexual activity is often only one instance of a spectrum of related risky behaviors (including tobacco, alcohol and substance abuse) that must be addressed consistently for the sake of teenagers' health.

*An explosion in the number and severity of STIs has been one result of the breakdown in sexual morality over the last 40 years. Gardasil® can help address one consequence of the spread of HPV, i.e. cervical cancer. At the same time, to best promote the health and happiness of adolescents, physicians, parents and social institutions should redouble their efforts to promote chastity. Consistent messages about and support for this virtue will not only help reduce disease, but will help individuals, couples, and marriages to flourish.*

## Important News



### ❖ Flumist® Delay

The North Dakota Immunization Program received information from the CDC that the distribution of state-supplied Flumist® for the upcoming influenza vaccination season would be delayed. We had requested that all state-supplied Flumist® doses would be delivered in August, September, and October. We have been notified that only 52.5 percent will be delivered by the end of October, with remaining doses delivered in November and December. We wanted to make you aware of this issue, so that you can schedule clinics accordingly. This is especially important for providers who are planning school-located vaccination clinics. At this time, we are not aware of any delays in the shipping of injectable doses. It is still anticipated that flu vaccine supplies for the upcoming season will be adequate.

### ❖ HPV Provider and Parent Surveys

The Immunization Program currently has a student working to complete her NDSU MPH

practicum with the North Dakota Department of Health, which will assess parental and provider attitudes on HPV vaccine recommendation. Through these surveys, we hope to determine the prevailing reasons for low HPV vaccine uptake in the state, in order to develop ways to increase HPV vaccine acceptance for our young people and ultimately prevent more HPV-related cancer. The survey can be found at [https://ndhealth.qualtrics.com/SE/?SID=SV\\_88GrGWoS0liFk4R](https://ndhealth.qualtrics.com/SE/?SID=SV_88GrGWoS0liFk4R).

### ❖ HPV Recall

The Immunization Program sent out HPV reminder/recall postcards on June 15, 2015. This is the first time postcards were sent to pre-teens and teens that have not started the HPV vaccine according to the North Dakota Immunization Information System (NDIIS). This first round of postcards was sent to the parents of all adolescents 11 through 17 years of age who have not started the HPV series. After this initial reminder/recall, postcards will be sent on a quarterly basis to those pre-teens who turned 11

during the quarter reminding them of the importance of HPV vaccination.

A complete schedule of all planned reminder/recall activities for 2015 as well as information about each activity and the letter and/or postcards being sent can be found on the immunization program website at:

<http://www.ndhealth.gov/Immunize/NDIIS/AdolescentRR.htm>.

Parents who no longer wish to receive reminder/recall postcards should visit the Immunization Program website at: [www.ndhealth.gov/immunize/](http://www.ndhealth.gov/immunize/) and fill out the Immunization Recall Exclusion form.

## ❖ 2014-15 School Immunization Rates

The 2014-2015 School Immunization Rates have been posted to our website and can be found at <http://www.ndhealth.gov/Immunize/Rates/>. The School Immunization Survey for the 2015-2016 School Year will be posted on October 1, 2015 and will be due November 13, 2015.

The 2015-2016 North Dakota school immunization requirements can be found at <http://www.ndhealth.gov/Immunize/Schools-ChildCare/>.

If you have any questions please contact the immunization program at 701.328.3386 or toll-free at 800.472.2180.

## Education Materials



August is National Immunization Awareness Month. To help you promote childhood immunization during NIAM and year

round, the National Center for Immunization and Respiratory Diseases (NCIRD) has printed additional copies of several of our childhood immunization posters. Limited quantities of these materials are available to order for free from the CDC warehouse.

These materials were developed based on formative research with parents and are co-branded with the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).

You can order copies of these materials at [CDC-INFO On Demand - Publications](#). (Enter the

PubID numbers below in the "Search for Text" field):

- Help Him Fight Measles With the Most Powerful Defense (English language poster): <http://www.cdc.gov/vaccines/events/niiw/promotional/print-materials/downloads/p-superbaby.pdf> - PubID number: 221563
- Stop Serious Diseases in Their Tracks Like You Do Your Curious Explorer (English language poster): <http://www.cdc.gov/vaccines/events/niiw/promotional/print-materials/downloads/p-explorer-baby.pdf> PubID number: 221900
- Poster - In the Battle Against Whooping Cough - She Needs More Than Cute (English language poster) <http://www.cdc.gov/vaccines/events/niiw/promotional/print-materials/downloads/p-bathtub-baby.pdf> PubID number: 221542





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## Calendar of Events

**August Lunch and Learn, August 12, 2015**

**September Lunch and Learn, September 9, 2015**

**National Vaccine Advisory Committee (NVAC)  
Meeting September 15 through 16, 2015 in  
Washington, D.C.**

**AAFP Assembly September 29 through October  
3, 2015 in Denver, CO.**

**October Lunch and Learn, October 14, 2015**

**ACIP Meeting October 21 through 22, 2015 in  
Atlanta, GA.**

**NFID Fall 2015 Clinical Vaccinology Course  
November 13 through 15, 2015 in North  
Bethesda, MD**

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Publication is available in alternative forms; for more information, contact Miranda Baumgartner, editor, *Immunization Newsletter*.

**EQUAL OPPORTUNITY EMPLOYER**

# Immunization Word Search

Once all the words in the puzzle have been found the remaining letters will reveal a hidden message.

p p m a r r e n n p t d t s h a  
n v e n d o h d o e e i e p a l  
e t a h c t a i i r t p v r s p  
u e s c p a r s t t a h o f h o  
m e l s c v s e a u n t i a i l  
o o e n a i l a z s u h s z n i  
c a s r e r n s i s s e t n g o  
o h e k e u y e n i t r o e l p  
c r o t e s c t u s i i n u e g  
c h i l d r e n m a d a o l s l  
a e s c e n t s m f r o m f h p  
l a c c o c o g i n e m v n c a  
c h i c k e n p o x n c e i r s  
r u b e l l a s i t i t a p e h

chickenpox  
children  
diphtheria

disease  
hepatitis  
HPV

immunization  
influenza  
measles

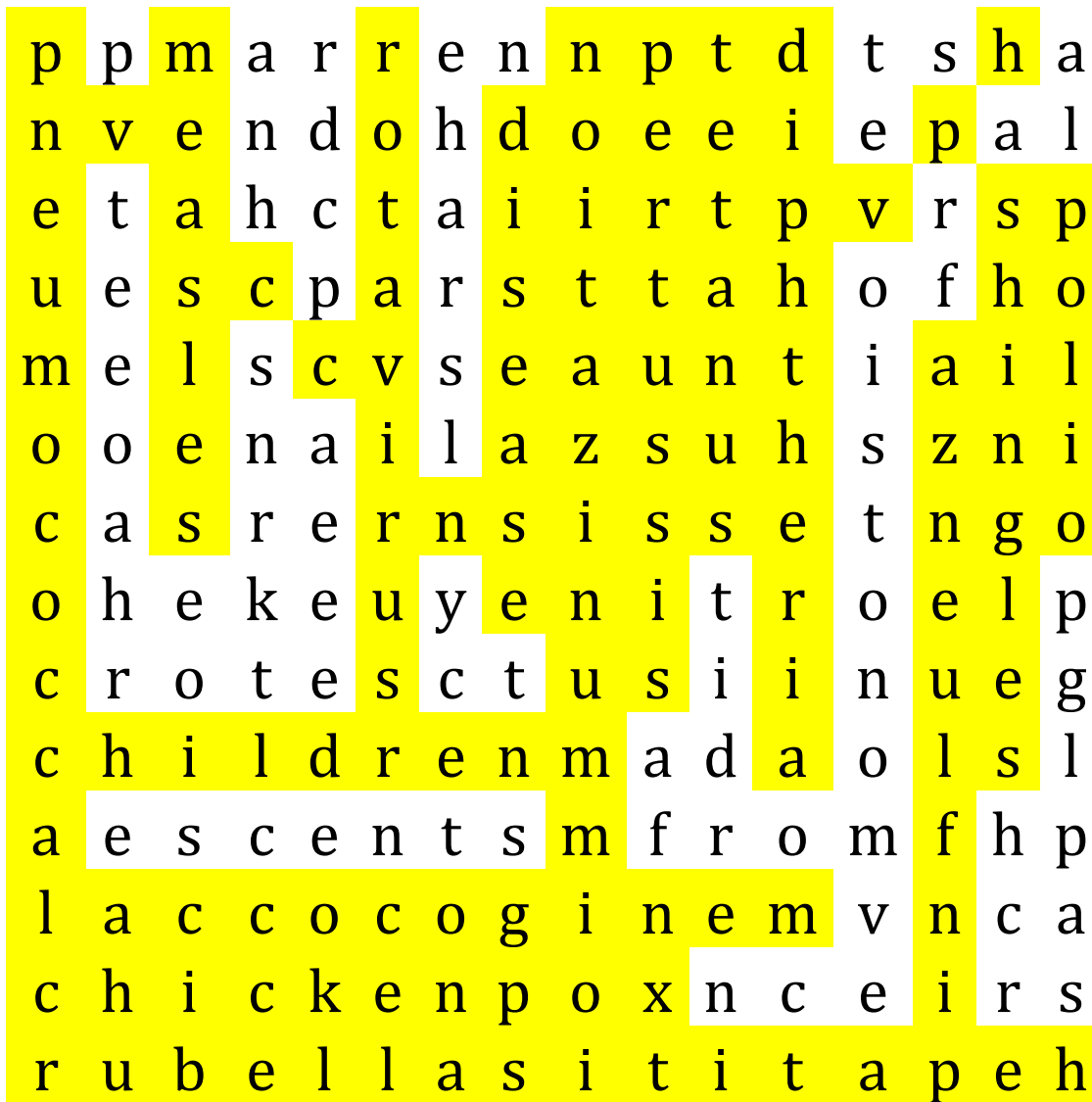
meningococcal  
pertussis  
pneumococcal

polio  
rotavirus  
rubella

- shingles
- tetanus
- vaccine

## Immunization Word Search Answer Key

Once all the words in the puzzle have been found the remaining letters will reveal a hidden message.



chickenpox  
children  
diphtheria

disease  
hepatitis  
HPV

immunization  
influenza  
measles

meningococcal  
pertussis  
pneumococcal

polio  
rotavirus  
rubella

shingles  
tetanus  
vaccine

P a r e n t s   a n d   h e a l t h   c a r e  
p r o f e s s i o n a l s   a r e   t h e  
k e y   t o   p r o t e c t i n g  
a d o l e s c e n t s   f r o m   H P V  
c a n c e r s .